Danish Medicines Agency

CERTIFICATE NUMBER: ***DK H 00132320***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Denmark confirms the following:
The manufacturer: ***Dune Medicare ApS***
Site address: ***Baldersbuen 29E, st.th., Hedehusene, 2640, Denmark***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***37149*** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-01-29*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packaging

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

2020-05-04

Name and signature of the authorised person of the Competent Authority of Denmark

Ms. Kathrine Ask Asmussen
Danish Medicines Agency
Tel: ***+45 93514252***
Fax:

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Tilladelse til virksomhed med euforiserende stoffer

Authorisation of activities with euphoriant substances

Lægemiddelstyrelsen godkender hermed, at
The Danish Medicines Agency hereby authorises

1.	Autorisationsnummer *Authorisation No.*	**39280**
2.	Virksomhed *Name of authorisation holder*	**Dune Medicare Aps**
3.	Med filial (erne) *With the site(s)*	**Baldersbuen 29E, st.th** **DK-2640 Hedehusene**
	Virksomhedsnummer *DKMA No.*	**267128**

udfører de i vedhæftede annekser nævnte aktiviteter
to carry out the activities mentioned in the Annexes attached

4.	Virksomhedens registrerede hovedadresse *Legally registered address*	**Baldersbuen 29E, st.th** **DK-2640 Hedehusene** **Virk.nr.** *DKMA No.* **267128**
5.	Tilladelsens gyldighedsområde *Scope of authorisation*	**Jf. Annex 1**
6.	Lovgrundlag for tilladelsen *Legal basis of authorisation*	Bekendtgørelse af lov om euforiserende stoffer § 2, stk. 2. *Consolidation act on the Danish act on euphoriant substances, section 2(2).* Bekendtgørelse nr. 557 af 31. maj 2011 om euforiserende stoffer. *Danish executive order on euphoriant substances*
7.	Ansvarlig for udstedelsen *Responsible officer*	**Gerd B. Linnebjerg, cand.pharm.** ***MSc Pharm***
8.	Underskrift *Signature*	Gerd Bdb Linnebjerg .....
9.	Ikrafttrædelsesdato *Applies as from*	**23. marts 2020** ***23 Marts 2020***
10.	Bilag *Annexes attached*	**Annex 1, Annex 2, Annex 3**

Det er en betingelse for opretholdelse af tilladelsen, at der ikke uden Lægemiddelstyrelsens forudgående godkendelse gennemføres ændringer i de forhold vedrørende virksomheden, der ligger som grundlag for udstedelsen. *It is a condition for maintaining the authorisation that no changes are made to the circumstances that form the basis of the authorisation.*
Fastsatte regler i gældende bekendtgørelse om euforiserende stoffer skal nøje overholdes. *The rules laid down in the current executive order on euphoriant substances must be strictly observed.*

Denne tilladelse erstatter tilladelse med aut. nr. 37657 *Substitutes authorisation with aut. no. 37657*

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

TILLADELSENS GYLDIGHEDSOMRÅDE **ANNEX 1**

Scope of the authorisation

GODKENDTE AKTIVITETER *AUTHORISED ACTIVITIES*	
▪ Der kan gives tilladelse til aktiviteter i henhold til bekendtgørelsen om euforiserende stoffer § 2 stk. 1, § 4 stk.3 og 5, § 5 nr. 5 og 7, § 7 stk. 1, § 8 stk. 1, § 9 stk. 1, § 14 stk. 1, § 16 stk. 1, § 19 stk. 1, § 20 stk. 1 og 4 samt § 23 stk. 1. *Authorisation can be granted pursuant to the Danish executive order on euphoriant substances, section 2(1), section 4(3) and (5,)section 5(5) and (7), section 7(1), section 8(1), section 9(1), section 14(1), section 16(1), section 19(1), section 20(1) and (4) and section 23(1).* ▪ Tilladelsen omfatter de på de angivede lister opførte stoffer samt salte og produkter heraf med mindre andet er anført. *The authorisation includes salts and products of the substances on the stated schedules unless any restriction has been given* ▪ *) Forud for hver forsendelse af euforiserende stoffer over landegrænsen skal separat import-/eksportcertifikat indhentes, som skal følge varen. *Prior to each shipment of euphoriant substances that is to cross the border, an import/export certificate must be obtained, and this certificate must follow the shipment.*	
E.1	**Modtagelse og besiddelse** ***Receipt and possession***
	Liste B stoffer *Schedule B substances* Liste E stoffer *Schedule E substances*
E.2	**Indførsel*** *Import*
	Liste B stoffer *Schedule B substances* Liste E stoffer *Schedule E substances*
E.3	**Udførsel*** *Export*
	Liste B stoffer *Schedule B substances* Liste E stoffer *Schedule E substances*
E.4	**Forhandling** *Trade*
	Liste E stoffer *Schedule E substances*
E.7	**Udlevering til videnskabeligt brug** *Distribution for scientific purposes*
	Liste B stoffer *Schedule B substances* Liste E stoffer *Schedule E substances*
E.8	**Udlevering til klinisk forsøg** *Distribution for clinical trials*
	Liste B stoffer *Schedule B substances* Liste E stoffer *Schedule E substances*

Begrænsninger eller uddybende bemærkninger til ovennævnte aktiviteter ***Restrictions or clarifying remarks related to the scope of these activities*:**
Ingen *None.*

ANNEX 2

Lager og distribution *Storage and distribution*			
Biofarma Logistik A/S Naverland 22 2600 Glostrup	Virk.nr. 57000	Dune Medicare Aps Baldersbuen 29E, st.th 2640 Hedehusene	Virk.nr. 267128

ANNEX 3

Ansvarlig over for Lægemiddelstyrelsen for så vidt angår de i Annex 1 anførte aktiviteter *Person responsible to the Danish Medicines Agency for the activities mentioned in Annex 1*
• Elise Hellesø Rinvar, cand. Pharm, QP og Direktør